

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

SANDRA J. PHILLIPS, et al.

Plaintiffs,

v.

BAPTIST MEDICAL CENTER-,
PRINCETON, et al.,

Defendants.

CV 03-AR-1078-S

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U.S. DISTRICT COURT
N.D. OF ALABAMA

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MEMORANDUM OPINION

Before the court is a motion to remand filed by plaintiff, Sandra J. Phillips ("Phillips"), as a class representative ("the plaintiff class"); motions to remand or in the alternative to sever and remand filed by defendants, Bryan Billions, M.D. and Birmingham Radiology Group, P.C., and by defendant, Baptist Medical Center-Princeton (collectively "the healthcare defendants"); and a motion to stay filed by the removing defendant, Wyeth, f/k/a American Home Products Corporation ("Wyeth"), pending the anticipated issuance of a Conditional Transfer Order by the Judicial Panel on Multi-District Litigation to the United States District Court for the Eastern District of Arkansas.

Facts

The underlying action was filed on January 6, 2003, in the Circuit Court of Jefferson County, Alabama, Bessemer Division. On February 5, 2003, defendant Wyeth on behalf of its unincorporated divisions, Wyeth Laboratories and Wyeth-Ayerst Pharmaceuticals ("Wyeth"), removed the action to this court on the ground of complete diversity of citizenship based on alleged fraudulent joinder of the non-diverse healthcare defendants. On February 26, 2003, this court

remanded the case to the state court. On April 12, 2003, Phillips amended her complaint seeking to represent as a class "each woman who at the time a prescription was written, was a resident of the State of Alabama and who filled a prescription, during the preceding six years, for Prempro." The putative class action complaint among other things sought the following relief:

After a full evidentiary hearing on the issues common to the class, for an Order declaring that Prempro causes cancer or causes an increased risk of cancer and declaring further that Prempro does not provide substantial health benefits and, upon entry of said Order, for an Order requirement that each class member be advised of the Courts finding and provide a method for delivery of a copy of the Court's Order to each class member.

On May 9, 2003, Wyeth removed the action for a second time to this court, asserting that the class action amendment presented a "substantial federal question" sufficient to create jurisdiction in this court over the entire action pursuant to 28 U.S.C. § 1331 because the Food and Drug Administration's ("FDA") regulation and labeling of Prempro was preemptive of the plaintiff class' state law claim, and because the otherwise non-removable claims of the healthcare defendants are properly removed when joined with a "separate and independent" claim raising a federal question pursuant to 28 U.S.C. § 1441(c). Wyeth contends that any request that the class be notified of the health benefits and risks of Prempro, a prescription drug, falls under the FDA's comprehensive regulatory scheme as labeling, and that the plaintiff class' request for an order stating that Prempro has no "substantial health benefits" squarely contradicts Prempro's FDA-approved labeling. Accordingly, Wyeth argues that the plaintiffs' claim is preempted under both a conflict theory of preemption and

under a theory of field preemption based on the FDA's comprehensive regulation of all labeling, advertising, and other communications regarding prescription drugs because Congress has vested the FDA with the sole responsibility of ensuring that pharmaceuticals sold in the United States are safe and effective and not misbranded pursuant to the comprehensive Food Drug and Cosmetics Act ("FDCA"). See 21 U.S.C. §§ 352(n), 355(c), 355(b)(1)(F), 355(d)(5), 355(d)(7), 393(b)(2)(B) and,; 21 U.S.C. §§ 331(a), 331(b), 331(k); see also 21 C.F.R. §§ 200.5, 202.1(1).

The plaintiff class and the healthcare defendants seek to have the entire action remanded to the state court, or in the alternative the healthcare defendants would have the court sever the class action claim and remand the remaining claims to state court.

Analysis

This court's federal question jurisdiction is governed by the "well-pleaded complaint" rule. Under that rule, "a case 'arises under' federal law and is therefore removable only if a federal claim exists on the face of [p]laintiff's complaint." *Dawson Ex Rel. Thompson v. Ciba-Geigy Corp.*, 145 F. Supp.2d 565 (D.N.J. 2001). In the instant action, Wyeth does not contend that the amended complaint raises a federal question on its face, but instead argues that the action fits within an exception to the "well-pleaded complaint" rule because of the preemptive power of the FDCA. The Eleventh Circuit in its recent decision, *Geddes v. American Airlines, Inc.*, 321 F.3d 1349 (11th Cir. 2003), explained the role of preemption in determining whether removal based on federal question jurisdiction was proper.

The court stated:

Preemption is the power of federal law to displace state law substantively. The federal preemptive power may be complete, providing a basis for jurisdiction in the federal courts, or it may be what has been called "ordinary preemption," providing a substantive defense to a state law action on the basis of federal law. More specifically, ordinary preemption may be invoked in both state and federal court as an affirmative defense to the allegations in a plaintiff's complaint. Such a defense asserts that the state claims have been substantively displaced by federal law. However, a case may not be removed to federal court on the basis of a federal defense, including that of federal preemption.

Complete preemption, on the other hand, is a doctrine distinct from ordinary preemption. Rather than constituting a defense, it is a narrowly drawn jurisdictional rule for assessing federal removal jurisdiction when a complaint purports to raise only state law claims. It looks beyond the complaint to determine if the suit is, in reality, "purely a creature of federal law," even if state law would provide a cause of action in the absence of the federal law. It transforms the state claim into one arising under federal law, thus creating the federal question jurisdiction requisite for removal to federal courts.

* * *

The Supreme Court and this Circuit have found complete preemption only under section 301 of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 185, and section 502 of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1132(a). The Supreme Court has cautioned that complete preemption can be found only in statutes with "extraordinary" preemptive force. Moreover, that "extraordinary" preemptive force must be manifest in the clearly expressed intent of Congress. Indeed, in "the absence of explicit direction from Congress," the Supreme Court has indicated its reluctance to find the extraordinary preemptive power necessary for complete preemption. Thus, the complete preemption inquiry turns on the question of "whether Congress not only intended for federal statute to provide a defense to state-law claims, but also intended to confer on defendants the ability to remove a case to a federal forum."

In summary, a federal law may substantively displace state law under ordinary preemption but lack the extraordinary force to create federal removal jurisdiction under the doctrine of complete preemption. If no other grounds for federal jurisdiction exist in such cases, then it falls to the state courts to assess the merits of ordinary preemption defense.

Id. at 1352-53 (internal cites omitted).

In light of *Geddes*, the question in the instant case becomes, whether the FDCA has the extraordinary preemptive force necessary to create federal removal jurisdiction. The place to begin the inquiry, as *Geddes* directs, is with Congressional intent in enacting the FDCA. In order to determine whether or not Congress intended complete preemption, the court must focus on whether the federal act in question provides for a federal right of action. If one does not exist, removal is not proper.

The FDCA, the act in question, was examined by the Supreme Court in *Merrell Dow Pharmaceuticals, Inc., v. Thompson*, 478 U.S. 804, 812 (1986). In *Merrell*, the Supreme Court found that Congress did not provide for a private right of action and by implication did not intend for cases like this one to be removed to federal court. *Id.* at 812. Furthermore in *Merrell*, the Supreme Court considered and rejected some of the same arguments raised by Wyeth here: 1) that interpretation of the FDCA labeling requirements was an element of the state law cause of action, and 2) that the federal interest in seeing that the FDCA was given uniform interpretation created federal jurisdiction. The *Merrell* Court held that when Congress determined that there was no private, federal cause of action for a violation, a state claim did not 'arise under' federal law. See also *Ciba-Geigy*, 145 F.Supp.2d at 571.

This court finds that preemption under the FDCA is not of the extraordinary kind that the Eleventh Circuit spoke of in *Geddes* and

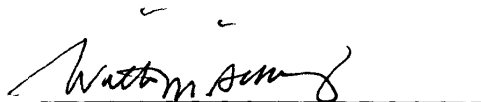
that is essential for removal based on federal question jurisdiction. A review of decisions by other courts that have looked at the issue of preemption under the FDCA reveals that other jurisdictions are in accord. *Ohler v. Purdue Pharma, L.P.*, no. 02-0757, 2003 WL 943643 (E.D. La. March 7, 2003) (court remanded finding no federal question jurisdiction based on the extensive regulation of prescription drugs by the Federal Food, Drug, and Cosmetic Act (FDCA)); *Gaul v. Neurocare Diagnostic, Inc.*, No. 02-CV-2135, 2003 WL 230800 (E.D. Pa. Jan. 1, 2003) (court held that federal jurisdiction was lacking where defendant could not establish an exception to the well-pleaded complaint rule because there was no private federal cause of action under the FDCA); *Jackson v. Purdue Pharma Co.*, No. 6:02-CV1428ORL19KRS, 2003 WL 21356783 (M.D. Fla. April 11, 2003) (court held lack of federal question jurisdiction rejecting defendant's argument that plaintiff's request for injunctive relief would displace the Congressionally mandated role of FDA in regulating prescription drug OxyContin); *Guckin v. Nagle*, ___ F. Supp. 2d ___, 2003 WL 2013175 (E.D. Pa. April 28, 2003) (court remanded case to state court based on defendant's failure to prove federal question jurisdiction under preemption theory involving the investigatory device exemption to the FDCA).

Conclusions

For the foregoing reasons, the court finds that there is no federal question jurisdiction upon which removal can be based. The motion to remand filed by the plaintiff class and the motions to remand filed by the healthcare defendants will be granted by separate order. The motion to stay filed by defendant Wyeth will be denied. A

separate order will issue.

DONE this 7th day of July 2003.

A handwritten signature in black ink, appearing to read "William M. Ackers, Jr.", is written over a horizontal line.

WILLIAM M. ACKER, JR.
UNITED STATES DISTRICT JUDGE